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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,688	12/14/2005	Pietro Bigoni	377/9-2178	1944

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WILLIAM J. SAPONE
COLEMAN SUDOL SAPONE P.C.
714 COLORADO AVENUE
BRIDGE PORT, CT 06605

EXAMINER	
TRUONG, THANH K	

ART UNIT	PAPER NUMBER
3721	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,688	BIGONI, PIETRO	
	Examiner	Art Unit	
	THANH K. TRUONG	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-28* is/are pending in the application.

4a) Of the above claim(s) *14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's RCE received on October 6, 2008.

2. Applicant's cancellation of claims 1-13 is acknowledged.

3. Claims 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on April 16, 2007.

4. Claims 14-28 are pending in the application.

5. Examiner's note: Young reference has been reinterpreted to clearly identify the first and second chambers.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monti (6,675,555) in view of Young (5,912,184).

Monti discloses a pharmaceutical packaging machine (automatic blistering machine) comprising:

at least two work areas arranged along a packaging line, the machine structure comprising:

enclosing panels assembled together to form enclosing chambers.

Monti discloses the claimed invention, but it does not disclose that the chambers are pressurized.

Young discloses an apparatus comprising: an environmentally enhanced enclosure that is pressurized to minimize contamination in the chamber.

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to modified Monti apparatus by incorporating the environmentally enhanced enclosure as taught by Young to provide a clean room environment and minimized the contamination in the enclosing chamber.

Monti modified by Young further discloses:

a first enclosing chamber (the I/O chamber – the chamber on the right hand side of figures 2B-2E) enclosing an environment at a pressure higher than an outside pressure (column 3, lines 17-21), and a second enclosing chamber (the process chamber – the chamber on the left hand side of figures 2B-2E) enclosing an environment with a pressure equal to the outside pressure (column 3, lines 48-49);

means for generating at least one flow of air into the chamber (Young - column 5, lines 21-22), suction means (18) to take the air out of the chambers to maintain substantially constant pressure inside the chamber (column 3, lines 19-26), and depuration means (16).

wherein the chambers communicate with each other via passages (not number) through which the air also passes between chambers (Monti – figure 1).

wherein the packaging machine (1) is automatic packaging pharmaceutical products in containers, band material (2) at least one feeding station (5), at least one station (4) for producing containers (Monti – figure 1).

at least one station (6) for closing containers (Monti – figure 1).

pressurized environment includes at least one mouth allowing band material along packaging line, the mouth having fluid barrier means for removing possible contaminating particles (13 – Young column 6, lines 34-40).

a plurality of panels (not number) formed the chambers and open spaces (not number) situated in the connection area allowing the air to go outside the chambers (Monti – figure 1).

means for generating flow of air into the chamber include at least one pump (a blower – Young, column 5, lines 21-22), depuration means (16) include filter (ULPA filters – figure 2B), sensor means (60, 61, 62) are connected to the filter means for detecting volume variation of the flow of air via control unit (36).

a main filter (16) situated in the introduction duct downstream of the pump (not number) and having connected thereto relative sensor (60, 61, 62).

Regarding claims 25, 26 and 28 (or cancelled claims 10, 11 and 13), since the Applicant did not traverse the Official Notice taken by the examiner in the previous office action (July 14, 2005), the well known in the art statement in the office action of May 31, 2007 (regarding claims 10, 11 and 13) is taken to be admitted prior art.

> (*Regarding the common knowledge modification previously taken (Official Notice), in order to adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common*

knowledge or well-known in the art. See 37 CFR 1.111(b). See MPEP 2144.03(c) and also Chevenard, 139 F.2d at 713, 60 USPQ at 241.)

It is old and well known (the admitted prior art mentioned above) in the art to employ a particular sensor (manostat sensor) to read the different pressure between the filters of the up stream and down stream of the air flow. Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the teaching from Monti and Young to device the apparatus as recited in claims 25, 26 and 28 to provide a more efficient packaging machine.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 18, 23, 24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoshima (6,368,208).

Minoshima discloses an apparatus comprising:

enclosing panel-shaped means (1, 10, 20), two enclosing chambers (10, 20); the pressure in chamber (10) is higher than an outside pressure, and the pressure in the second chamber (20) equal to the outside pressure;

means (14) for generating flow of high pressure air into the first chamber (10);

passage (28) provided between the first and second chambers;

suction means (25) for withdrawing air from second chamber (20) to maintain the pressure inside the second chamber substantially constant and equal to the outside pressure;

means (9, 31, 32) cooperating with the generating means and with suction means for purifying a flow of air at an outlet of the second enclosing chamber.

Regarding 23, 24 and 27, Minoshima further discloses:

a plurality of panels (not number) formed the chambers and open spaces (not number) situated in the connection area allowing the air to go outside the chambers (Minoshima – figures 1-3).

means for generating flow of air into the chamber include at least one pump (14), depuration means (9, 31, 32), sensor means (41) are connected to the filter means for detecting volume variation of the flow of air via control unit (42).

a main filter (32) situated in the introduction duct downstream of the pump and having connected thereto relative sensor.

10. Claims 19-22, 25, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoshima (6,368,208) in view of Monti (6,675,555).

As discussed above, Minoshima discloses the claimed invention, but it does not expressly disclose the pharmaceutical product packaging machine.

Monti discloses a pharmaceutical packaging machine (automatic blistering machine) comprising: at least two work areas arranged along a packaging line, the

machine structure comprising: enclosing panels assembled together to form enclosing chambers.

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to incorporate the clean room environment as taught by Minoshima into a pharmaceutical packaging machine of Monti to provide a clean room environment and minimized the contamination in the production of pharmaceutical products.

Regarding claims 19-22, Minoshima modified by Monti further discloses:

wherein the chambers communicate with each other via passages (not number) through which the air also passes between chambers (Monti – figure 1).

wherein the packaging machine (1) is automatic packaging pharmaceutical products in containers, band material (2) at least one feeding station (5), at least one station (4) for producing containers (Monti – figure 1).

at least one station (6) for closing containers (Monti – figure 1).

Regarding claims 25, 26 and 28 (or cancelled claims 10, 11 and 13), since the Applicant did not traverse the Official Notice taken by the examiner in the previous office action (July 14, 2005), the well known in the art statement in the office action of May 31, 2007 (regarding claims 10, 11 and 13) is taken to be admitted prior art.

> *(Regarding the common knowledge modification previously taken (Official Notice), in order to adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See MPEP 2144.03(c) and also Chevenard, 139 F.2d at 713, 60 USPQ at 241.)*

It is old and well known (the admitted prior art mentioned above) in the art to employ a particular sensor (manostat sensor) to read the different pressure between the filters of the up stream and down stream of the air flow. Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified the teaching from Minoshima and Monti to device the apparatus as recited in claims 25, 26 and 28 to provide a more efficient packaging machine.

Response to Arguments

11. Applicant's arguments filed July 14, 2008 have been considered but are moot in view of the new ground(s) of rejection.

12. As discussed above in paragraphs 5-7, Young reference has been reinterpreted to clearly identify the first and second chamber – the examiner indicated that the first chamber is the i/o chamber that located on the right hand side of figures 2B-2E, and the process chamber next to it on the left hand side is the second chamber.

13. In response to the Applicant's argument that item (18) in Young "*cannot meet the limitation for "suction means"*", the examiner disagrees. Young clearly labeled item (18) as "facility exhaust vacuum" and this clearly implies that air is being removed or being drawn away from the enclosure by means (18) – hence it is read as "suction means". Furthermore, it is construed that the word "vacuum" clearly implies "suction means".

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thanh K. Truong whose telephone number is 571-272-4472. The examiner can normally be reached on Mon-Fri 9:00AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tkt
December 19, 2008.

/Thanh K Truong/
Primary Examiner, Art Unit 3721.